

Policies Repository



Policy Title Sildenafil (Revatio®)

Policy Number FS.CLIN.1

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This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Sildenafil (Revatio®)** is indicated for the treatment of pulmonary arterial hypertension (World Health Organization [WHO] Group I) to improve exercise ability. There are two types of pulmonary arterial hypertension. Primary pulmonary arterial hypertension (PPAH) is inherited or occurs for no known reason. Secondary pulmonary arterial hypertension (SPAH) occurs as a result of conditions such as chronic heart or lung disease, blood clots in the lungs, or scleroderma.

The use of sildenafil (Revatio®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description **Sildenafil (Revatio®)** is a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase-5 (PDE5) in the smooth muscle of the pulmonary arteries, where cGMP is degraded by PDE5. As a result, sildenafil (Revatio®) increases cGMP within the pulmonary arteries, causing relaxation and vasodilation of the pulmonary arteries. Individuals treated with sildenafil (Revatio®) have improved physical functioning as evidenced by increased walking distances, reduced blood pressure in the pulmonary arteries, and increased cardiac outputs.

Sildenafil delayed clinical worsening in patients with pulmonary arterial hypertension (PAH) currently stabilized on intravenous epoprostenol in a randomized, double-blind, placebo-controlled clinical study (n=267). Patients with primary pulmonary hypertension treated with oral sildenafil have experienced substantial hemodynamic and symptomatic improvements (Sastry et al, 2004; Jackson & Chambers, 2002; Zimmermann et al, 2002; Bigatello et al, 2000). Sildenafil, in combination with prostacyclin analogues (ie, beraprost, iloprost, epoprostenol), has been shown to be beneficial in patients with pulmonary hypertension (Stiebellehner et al, 2003; Watanabe et al, 2002; Ghofrani et al, 2002). In a retrospective study (n=25), treatment with sildenafil produced a clinical improvement in pulmonary

hypertension (PH) in 88% of infants with chronic lung disease (Mourani et al, 2008).

Policy Guideline Inclusion

Sildenafil (Revatio®) is approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of pulmonary arterial hypertension
- No history of a nitrate prescription being filled within the last six months

Policy Guideline Exclusion

Sildenafil (Revatio®) is denied when any of the following exclusion criteria are present:

- Documentation of a diagnosis other than pulmonary arterial hypertension
- A history of a nitrate prescription being filled within the last six months

Policy List of Applicable Drugs

| Brand Name | Generic Name |
|------------|--------------|
| Revatio | Sildenafil |

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

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McNamara TC. Written communication regarding prior authorization criteria; July 2001.

Mourani PM, Sontag MK, Ivy DD, et al: Effects of Long-Term Sildenafil Treatment for Pulmonary Hypertension in Infants with Chronic Lung Disease. *J Pediatr* 2008; Epub:epub-epub.

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Revatio® [package insert]. New York, NY: Pfizer, Inc.; 2007. Also available online at: http://www.pfizer.com/files/products/uspi_revatio.pdf. Accessed November 5, 2009.

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Stiebellehner L, Petkov V, Vonbank K, et al: Long-term treatment with oral sildenafil in addition to continuous IV epoprostenol in patients with pulmonary arterial hypertension. *Chest* 2003; 123(4):1293-1295.

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Policy Link to Related Policies

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